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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,567	09/08/2003	Yvette M. Fobian	02-760-A	1863

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EXAMINER

COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,567

Applicant(s)

FOBIAN ET AL.

Examiner

Janet L. Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 1-11 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-22 pending in the instant application.

Response to Election/Restrictions

1. Receipt is acknowledged of Applicants' Response, filed March 14, 2005, in response to the Restriction Requirement of February 14, 2005, which has been reviewed by the Examiner and entered of record in the file. Applicants' election of Group II, **without** traverse, of claims 1-11 in part, drawn to heterocyclic compounds, is acknowledged. The Examiner notes that claims 21 and 22 in part should have been included in this group, and rejoins them at this time.

Therefore, claims 12-20 withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, i.e. Groups I, III, and IV, there being no allowable generic or linking claim.

Status of the Claims

2. Applicants have further elected the species of Compound No. 9 found on page 179 of the specification, i.e. the compound of the formula: (2R,3S)-3-amino-4-(3,5-difluorophenyl)-1-(1-(3-ethynylphenyl)cyclopropylamino)butan-2-yl-3-(dipropylcarbamoyl)-5-(oxazol-2-yl)benzoate. The claims that fall within the examined invention are 1-11, 21, and 22 (all in part). Claims 1-11, 21, and 22, 12-20, drawn to non-heterocyclic compounds, as well as methods, withdrawn from further consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b), as directed to non-elected subject matter, since they fall outside the class and subclasses of the elected compound.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-11, 21, and 22, in part, provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-346 of copending Application No. 10/291,318, filed November 8, 2002, with a common inventor. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite genuses of amino-hydroxy derivatives with the same core structure and variables that overlap in definition. The '218 application discloses a similar genus of diamine derivatives with beta-secretase inhibitory activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

5. Claims 1-11 and 21 objected to as containing non-elected subject matter.

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Conclusion

6. In conclusion, claims 1-22 are pending, however claims 12-20 are withdrawn from consideration as directed to non-elected subject matter. Claims 1-11, 21, and 22 are currently rejected, and claims 1-11 and 21 are objected to.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
May 31, 2005

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

for Kamal Saeed
Joseph K. McKane,
SPE, Art Unit 1626